



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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December 3, 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: The HED Chapter of the Reregistration Eligibility
Decision Document (RED) for Peroxy Compounds, Case
#4072

FROM: Jane Smith, Chemist *CHM*
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THRU: Esther Saito, Branch Chief *Fla Chen - for*
Chemical Coordination Branch
Health Effects Division (7509C) *3 Dec 93*
and
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Health Effects Division (7509C) *12/2/93*

TO: Jay Ellenberger, Chief
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Special Review and Reregistration Branch (7508W)

Attached is the Human Health Assessment for Hydrogen peroxide, peroxy acetic acid, and potassium peroxymonosulfate by HED for inclusion in the Reregistration Eligibility Decision Document.

Peroxides are highly reactive chemicals evident from the acute effects observed from exposure to these compounds by the dermal or ocular routes (Toxicity Category I). In contrast, exposure by the oral route does not appear to be acutely toxic (Toxicity Category III).

Hydrogen peroxide and peroxyacetic acid are used for industrial/commercial floors, medical equipment, e.g., dialysis parts, catheters, surfaces, furniture, equipment, etc and residential bathroom surfaces. These chemicals are also used in dairy/cheese processing plants, on food processing equipment and in pasteurizers in breweries, wineries, and beverage plants. Both of these compounds are generally recognized as safe (GRAS) according to the Food and Drug Administration (21 CFR §178.1010 Sanitizing solutions) when used on food-processing equipment, utensils, and other food-contact articles. Dietary exposure is possible; however, these chemicals react instantly upon contact



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with materials such as food and are degraded to moieties which present no toxicological concern. Through the use of protective equipment exposure to applicators/mixers is minimized.

Potassium peroxymonosulfate in the form of a soluble concentrate/liquid is used as a water bed disinfectant. The soluble concentrate/solid is diluted for spraying/misting/fogging poultry houses, hatcheries and processing plants. This is considered a non-food use and no dietary exposure is expected to occur as a result of pesticidal/disinfectant uses. Through the use of protective equipment exposure to applicators/mixers is minimized.

Based on the pesticidal use patterns, the human risks are considered to be negligible. No additional hazard or exposure data are required for reregistration eligibility for these compounds.

Labeling requirements

All end-use product labels for commercial/industrial uses and medical uses must include protective equipment including protective clothing, rubber gloves and goggles, face shield or safety glasses. Thorough washing with soap and water after handling (including clothing) should also be recommended. These label requirements should appear as appropriate based on the end-use product toxicity.

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B. Human Health Assessment

1. Toxicology Assessment

The toxicological data for hydrogen peroxide, potassium peroxymonosulfate, and peroxyacetic acid are summarized below. The data are adequate and will support reregistration eligibility of these compounds.

a. Acute Toxicity

Table I: Acute Toxicity - Hydrogen Peroxide		
Test	Result [*]	Category
Acute Oral LD ₅₀ (mouse)	2000 mg/kg	III
Acute Dermal LD ₅₀ (rat)	4060 mg/kg	III
Acute Inhalation LC ₁₀ (mouse)	227 ul/L	II
Eye Irritation (rabbit)	severe irritation	I
Dermal Irritation (rabbit)	corrosive	I
Skin Sensitization	-	-

^{*} SAX, Irving N. and Lewis, Richard J., "Dangerous Properties of Industrial Materials" Seventh edition, Van Nostrand Reinhold, 1989, H116000.

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Table II: Acute Toxicity - Peroxyacetic acid

Test	Result [*]	Category
Acute Oral LD ₅₀ (rat)	1540 mg/kg	III
Acute Dermal LD ₅₀ (rabbit)	1410 mg/kg	II
Acute Inhalation LC ₅₀ (rat)	0.450 mg/L	II
Eye Irritation (rabbit)	severe irritation	I
Dermal Irritation (rabbit)	corrosive	I
Skin Sensitization	-	-

^{*} SAX, Irving N. and Lewis, Richard J., "Dangerous Properties of Industrial Materials" Seventh edition, Van Nostrand Reinhold, 1989, PCL500

Table III: Acute Toxicity - Potassium Peroxymonosulfate

Test	Result	Category
Acute Oral LD ₅₀ (rat) ¹	1287 mg/kg (♀) 1129 mg/kg (♂)	III
Acute Dermal LD ₅₀ (rat) ²	> 2000 mg/kg	III
Acute Inhalation LC ₅₀ (rat) ³	> 5.0 mg/L	IV
Eye Irritation (rabbit) ⁴	severe corneal opacity	I
Dermal Irritation (rabbit) ⁵	corrosive	I
Skin Sensitization (guinea pig) ⁶	negative	n/a ⁷

¹ 81-1, MRID 426074-01

² 81-2; MRID 426074-02

³ 81-3; MRID 425912-01

⁴ 81-4; MRID 426074-03

⁵ 81-5, MRID 426074-04

⁶ 81-6, MRID 426074-05

⁷ n/a = not applicable

b. Other Toxicological Considerations

Hydrogen peroxide, peroxyacetic acid, and potassium peroxymonosulfate are oxidizing agents; in general, the organic peroxides are stronger oxidants than hydrogen peroxide. It is well known that peroxides react (sometimes violently) with materials containing reducing agents, and concentrated materials are routinely handled with care because of the potential for strong chemical reactions. The high reactivity of the peroxides are evident from the acute effects observed from exposure to these compounds by the dermal or ocular routes. They are corrosive and severely irritating to the eyes, skin and mucous membranes (Toxicity Category I). In contrast, exposure by the oral route does not appear to be acutely toxic (Toxicity Category III). Therefore, specifically because of these very reactive properties and moderately low oral toxicity, dilute concentrations of peroxides have found wide applications and safe use as disinfectants.

Based on the chemical reactivity of peroxides, these compounds would be expected to have biological activity, particularly with macromolecules. Hydrogen peroxide, for example, is a known mutagenic compound with activity in such assays as the Salmonella assay (Ames test), aberrations and sister chromatid exchanges in cultured mammalian cells, and for DNA damage and repair in cultured human fibroblasts.

2. Exposure Assessment

a. Dietary Exposure

Hydrogen peroxide and peroxyacetic acid are used in dairy/cheese processing plants, on food processing equipment and in pasteurizers in breweries, wineries, and beverage plants. Although some contact may occur between treated equipment and food, no residues are expected since only trace amounts would come in contact with food having contacted treated equipment and both compounds degrade rapidly (in air) primarily to oxygen and water or oxygen and acetic acid. In addition, both of these compounds are generally recognized as safe (GRAS) according to the Food and Drug Administration (21 CFR §178.1010 Sanitizing solutions) when used on food-processing equipment, utensils, and other food-contact articles. Dietary exposure is possible; however, these chemicals react instantly upon contact with materials such as food and are degraded to moieties which present no toxicological concern.

Potassium peroxymonosulfate is used in poultry houses, hatcheries and processing plants. These uses involve removal of the animals or

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meat/eggs before use, followed by a potable water rinse and time for drying before re introducing the poultry. In processing houses, the uses are limited to floors, ceilings, and walls. This active ingredient is not used directly on poultry/meat. This is considered a non-food use and no dietary exposure is expected to occur as a result of pesticidal/disinfectant uses.

b. Occupational and Residential Exposure

Hydrogen peroxide and peroxyacetic acid, in the form of a soluble concentrate/liquid, are used for industrial/commercial floors, medical equipment, e.g., dialysis parts, catheters, surfaces, furniture, equipment, etc and residential bathroom surfaces. It is also used in dairy/cheese processing plants on food processing equipment and in pasteurizers in breweries, wineries, and beverage plants. Applications are primarily by immersion, mop, sponging or wipe-on, and spraying. There is a potential for applicator/mixer exposure. Considering these compounds are corrosive and severely irritating to the skin, eyes and mucous membranes (Toxicology Category I), exposure is a concern. However, protective equipment is required on the labels including protective clothing, rubber gloves and goggles, face shield or safety glasses. Thoroughly washing with soap and water after handling (including clothing) is recommended. The use of protective equipment sufficiently minimizes the exposure to applicators/mixers.

Potassium peroxymonosulfate in the form of a soluble concentrate/liquid is used as a water bed disinfectant. The soluble concentrate/solid is diluted for spraying/misting/fogging poultry houses, hatcheries and processing plants. Based on these uses dermal and inhalation exposure to applicators/mixers is expected. Considering this chemical is corrosive and causes severe eye, skin and mucous membrane irritation (Toxicology Category I) protective equipment is required on the labels including protective clothing, rubber gloves and goggles, face shield or safety glasses. Thoroughly washing with soap and water after handling (including clothing) is recommended. Through the use of protective equipment exposure to applicators/mixers is minimized.

There is a potential for post-application exposure; however based on the current uses exposure is expected to be minimal.

Labeling requirements

All end-use product labels for commercial/industrial uses and medical uses must include protective equipment including protective clothing, rubber gloves and goggles, face shield or safety glasses. Thorough washing with

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soap and water after handling (including clothing) should also be recommended. These label requirements should appear as appropriate based on the end-use product toxicity.

3. Risk Characterization

The Agency has a concern for an acute risk based on Toxicology Category I for skin and eye irritation. The acute risk from occupational exposure to these three corrosive compounds is minimized through the use of protective equipment. There is essentially no dietary exposure to these compounds based on these uses; therefore, no risk is associated with dietary or chronic exposure. Based on these factors and the pesticidal use patterns, the human risks are considered to be negligible. No additional hazard or exposure data are required for reregistration eligibility for these compounds.

END